PULPDENT CORPORATION

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K120003

APR - 5 2012

510(k) SUMMARY

December 28, 2011

Contact:
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Telephone: 617-926-6666
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DEVICE:

Trade Name: ***NuCal***
Classification Name: Calcium hydroxide cavity liner.
FDA Product Code: 76 EJK, 21 CFR Part 872.3250

PREDICATE DEVICES:

Pulpdent *TempCanal*
Pulpdent *Multi-Cal*
UltraDent *UltraCal XS*

INTENDED USE: *NuCal* is used by the dental professional as a cavity liner and as a temporary root canal dressing.

DESCRIPTION: *NuCal* is a non-setting, pre-mixed, radiopaque calcium hydroxide paste that has a pH > 12, is easily removed from the root canal with water, has been designed for ease of handling and will flow through a 27 gauge applicator tip.

COMPARISON WITH PREDICATE PRODUCTS:

NuCal is substantially equivalent in design, composition, performance and intended use to the predicate products:

PRODUCT	DESCRIPTION	INTENDED USE	COMPOSITION
NuCal	Non-setting, pre-mixed, radiopaque calcium hydroxide paste	Cavity liner and temporary root canal dressing.	Calcium hydroxide Barium sulfate Polyethylene glycol Water
Pulpdent *TempCanal* K944945	Non-setting, pre-mixed, radiopaque calcium hydroxide paste	Cavity liner and temporary root canal dressing.	Calcium hydroxide Barium sulfate Aqueous gel matrix
Pulpdent *Multi-Cal* K944945	Non-setting, pre-mixed, radiopaque calcium hydroxide paste	Cavity liner and temporary root canal dressing.	Calcium hydroxide Barium sulfate Aqueous gel matrix
UltraDent *UltraCal XS* K970114	Non-setting, pre-mixed, radiopaque calcium hydroxide paste	Cavity liner and temporary root canal dressing.	Calcium hydroxide Barium sulfate Aqueous matrix

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SUMMARY OF PERFORMANCE TESTING – BENCH

The following test results demonstrate that *NuCal* performs as intended:

Appearance	Thin white paste.
Consistency	Smooth, homogenous, thin paste.
Paste characteristic	Dispenses easily through 27 gauge applicator tip without clogging or force.
Specific gravity	1.470 g/ml
pH	> 12
Radiopacity	Equal to the same thickness of aluminum
Shelf life	Two years, based on accelerated testing at 37°C

CONCLUSION:

From the above comparisons, the bench testing and the decades of organizational experience with calcium hydroxide preparations, it can be concluded that *NuCal* is substantially equivalent in design, composition, performance and intended use to the predicate products listed above. The predicate products have been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3250 and have been used by dental professionals for more than 20 years. A search of the relevant scientific literature shows that calcium hydroxide pastes used for cavity lining and root canal dressing have been studied since the 1950's. See References below.

REFERENCES

1. American Dental Association. Accepted Dental Therapeutics, 39th edition. Calcium hydroxide preparations. 1982 July; 300-301.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Kenneth J. Berk
Director
Pulpdent Corporation
80 Oakland Street
Watertown, Massachusetts 02472

APR - 5 2012

Re: K120003
Trade/Device Name: Nucal
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium Hydroxide Cavity Liner
Regulatory Class: II
Product Code: EJK
Dated: February 17, 2012
Received: February 21, 2012

Dear Mr. Berk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K120003

Device Name: *Pulpdent NuCal*

Indications For Use:

NuCal is a non-setting, pre-mixed, radiopaque calcium hydroxide paste used as a cavity liner and as a temporary root canal dressing.

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120003